

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Date: March 29, 2000

0083 '00 APR -5 AIO:08

Re: 99P-1340/CP 1 — Petition to Have *Eternity* eau de parfum declared "Misbranded"

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity* eau de parfum declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to fragrance products I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- | | | | |
|---|---|--|--|
| <input type="checkbox"/> anaphylaxis/shock | <input type="checkbox"/> double vision | <input checked="" type="checkbox"/> incoherence | <input checked="" type="checkbox"/> nausea |
| <input checked="" type="checkbox"/> anxiety, restlessness | <input checked="" type="checkbox"/> ear pain | <input checked="" type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input type="checkbox"/> asthma | <input type="checkbox"/> eczema | <input checked="" type="checkbox"/> irritability | <input checked="" type="checkbox"/> rashes |
| <input checked="" type="checkbox"/> breathing difficulty | <input checked="" type="checkbox"/> eyes, watery or dry | <input checked="" type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input type="checkbox"/> bronchitis | <input checked="" type="checkbox"/> fatigue | <input checked="" type="checkbox"/> laryngitis | <input checked="" type="checkbox"/> short-term mem. loss |
| <input checked="" type="checkbox"/> can't concentrate | <input checked="" type="checkbox"/> flushing | <input checked="" type="checkbox"/> lethargy | <input type="checkbox"/> sinusitis |
| <input checked="" type="checkbox"/> coughing | <input type="checkbox"/> headaches | <input type="checkbox"/> lymph nodes swell | <input type="checkbox"/> sneezing |
| <input checked="" type="checkbox"/> depression | <input checked="" type="checkbox"/> heart beat irregularity | <input checked="" type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input checked="" type="checkbox"/> disorientation | <input type="checkbox"/> hives | <input checked="" type="checkbox"/> muscle pain/weakness | <input type="checkbox"/> swallowing difficulty |
| <input checked="" type="checkbox"/> dizziness | <input type="checkbox"/> hypertension | <input type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus |
| <input checked="" type="checkbox"/> other: <u>vascular swelling</u> | | | |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Soni Temple
your name

6179 Stratford Dr, Palm HTS, OH 44130
address; city/st/zip

99P-1340

* Children exposed suffer w/ depression, learning disabilities, attention deficit
Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and WRITE the FDA... today!

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SYMPTOMS AND HEALTH EFFECTS OF MCS INCLUDE

- * Confusion
- * Numbness
- * Depression
- * Skin Rashes
- * Memory Loss
- * Arthritis
- * Other Rheumatoid Illnesses
- * Sensitivity to Perfumes and Scented Products
- * Anxiety
- * Fatigue
- * Asthma
- * Sinusitis
- * Nausea
- * Light-Headedness

MCS may "mimic" numerous other diseases. The key is to determine *when* these symptoms occur (during or after chemical exposure), and observe whether symptoms dissipate upon removal from (or avoidance of) the suspected cause. Keep a "diary" to record these observations and ask your physician to utilize the environmental questionnaire published by the Institute of Medicine.

A FEW FACTS ABOUT MCS

Anyone can become chemically sensitive, however, children, pregnant women and the elderly are the most vulnerable.

MCS may be prevented or mitigated by early recognition of the symptoms and an accurate medical diagnosis.

Symptoms can be reduced by implementing safer lifestyle choices. For example: reduce your exposure to synthetic products and eat foods free of chemicals, preservatives, dyes and other additives.

Ohio Network for the Chemically Injured
P.O. Box 29290
Parma, OH 44129

OHIO NETWORK FOR THE CHEMICALLY INJURED

O.N.F.C.I. supports those with Multiple Chemical Sensitivity (MCS), a disability caused by one major exposure or chronic low-level exposures to chemicals in our everyday environment. Many are suffering from MCS, including those diagnosed with Chronic Fatigue Syndrome, Fibromyalgia, Gulf War Syndrome, Connective Tissue Disease from implants, and Environmental Illness.

MCS is recognized as a qualifying disability by many U.S. Government agencies, including HUD, the Social Security Administration and the National Institute of Environmental Health Sciences (NIEHS). Those with MCS are protected under the Americans with Disabilities Act.

PREVENTING DISABILITY THROUGH:
AWARENESS ADVOCACY
SUPPORT
EDUCATION (Members/Community)

CHEMICALS MAY BE AFFECTING YOUR HEALTH

CHEMICALS, SMOKE TRIGGER SYMPTOMS IN SOME PEOPLE

Stimuli that can trigger reactions in a Multiple Chemical Sensitivity sufferer are as varied as the side effects. Listed here are a number of chemical sources that have been known to both cause and/or aggravate the condition.

- * Maintenance chemicals, including strong cleaning disinfectants, carpet shampoos, waxes and polishes
- * Cigarette smoke
- * Pesticides along with "poisoned pansies" (cut flowers that may be loaded with pesticides, fungicides and insecticides.)
- * Paneling, desks, shelving and furniture that may contain chemicals, such as formaldehyde, that have not "gassed out"
- * New carpeting, along with the foam padding and glue used for installation
- * Fragrance emission devices, such as room air deodorizers
- * Odors emitted from copy and fax machines, computers, office machines, and treated papers
- * Everyday products such as solvents, lacquers, perfumes, deodorants, hair sprays, body and laundry soaps, fabric softeners, dry cleaning and gasoline

"Use of spray aerosols shall be prohibited when children are in attendance at the child daycare center." Ohio Law, ODHS 1286 (10) (Rev. 6/95) for Child Day Care Center Licensing Rules.

O.N.F.C.I.

Supports Its Members Through:

AWARENESS

- * Information Distribution
- * Newspaper Articles and Personal Profiles
- * Healthier Hospitals on the Horizon Campaign

EDUCATION

- * Literature distribution - information resources
- * Meeting speakers on related MCS topics
- * Interaction with the media, business, industry, medical organizations and associations, and government agencies

ADVOCACY

- * Contact with legislators, the media and government agencies
- * Americans with Disabilities Act (ADA) issues related to medical care, employment and other access needs.
- * Maintain working relationships with government agencies such as the Ohio Governor's Council on People with Disabilities and other disability groups such as Services for Independent Living Centers

SUPPORT

- * Monthly support group and education meetings
- * Networking and Referrals
- * Information Resources

For further information, contact:

**The Ohio Network for the
Chemically Injured**
P.O. Box 29290, Parma, Ohio 44129
Toni Temple, Chair (440) -845-1888
Dora McGregor, Co-Chair (440)-543-6687

RESOURCES AT A GLANCE:

O.N.F.C.I. SUPPORT GROUP MEETING

Call ONFCI for further information:
(440)-845-1888 or (440)-543-6687

OHIO GOVERNOR'S COUNCIL ON PEOPLE WITH DISABILITIES

400 E. Campus View Blvd., Columbus OH
(800) 282-4536 or (614) 438-1391

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

ATSDR - Free information on toxic chemicals and their health effects.
(888)-422-8737

AMERICAN ACADEMY OF ENVIRONMENTAL MEDICINE

(316) 684-5500

Your local public and medical libraries as well as computer networks, are excellent educational resources for MCS issues.

NATIONAL NEWSLETTERS

Canary News
1404 Judson Avenue
Evanston, IL 60201
(847) 866-9630

Human Ecologist
H.E.A.L. (Human Ecology Action League)
P.O. Box 49126
Atlanta, GA 30359-1126

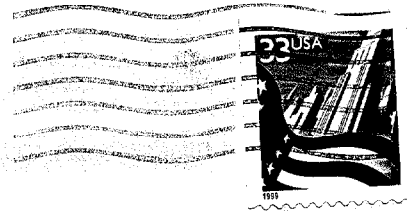
Our Toxic Times
Chemical Injury Information Network
P.O. Box 301
White Sulphur Springs, MT. 59645
(406)-547-2255

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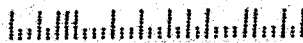
Antoinette Temple
6179 Stratford Dr
Cleveland OH 44130-2362

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